K083098

Premarket Notification 510(k) Summary
As required by section 807.92
Navigator Applications Suite

APR - 1 2009

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare Finland OY
C/O Datex-Ohmeda
PO Box 7550
Madison, WI 53707 USA
Tel: 608-221-1551
Fax: 608-223-2496

NAME OF CONTACT:

Ms. Adrienne Lenz, RAC
Ms. Karla Krause (alternate)

DATE:

October 14, 2008

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Navigator Applications Suite

COMMON NAME:

Navigator Applications Suite

CLASSIFICATION NAME:

BSZ, Accessory to gas machine for anesthesia or analgesia

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Navigator Applications Suite is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Navigator Applications Suite (K071097, K081941).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Navigator Applications Suite is a product that integrates information from an anesthesia delivery system, intravenous drug infusion pumps, and patient monitor. It works in a standalone or networked environment. The three main functions of the Navigator are:

- Navigator Therapy: Visualization of the modeled effect of the anesthesia drugs on the patient displayed on a point-of-care Navigator computer. The visualization is based on pharmacokinetic and pharmacodynamic (PK/PD) models and multi-drug models. Navigator also supports automatic data capture from supported intravenous drug infusion pumps and patient monitors to minimize manual data entry
- Navigator Protocol: Framework to enable access to facility-selected care protocols at the point of care.
- Navigator Device: Electronic and interactive instructions for users to address technical issues with anesthesia delivery systems.

INTENDED USE as required by 807.92(a)(5)

Navigator Applications Suite (Navigator) is a software package that includes Navigator Therapy, Navigator Protocol and Navigator Device. Navigator software is loaded into a medical grade PC physically mounted to the Anesthesia Delivery System and receives data from supported Anesthesia Delivery Systems, Anesthesia Patient Monitors and Intravenous Drug Infusion Pumps.

Navigator Therapy displays pharmacokinetic, pharmacodynamic (PK/PD) and synergistic PD modeling information. Navigator Therapy provides the heath care provider with information about the modeled effect of supported anesthesia pharmaceuticals delivered to the patient.

Models only apply to the following patient populations:

Age:	18 - 90 years old
Weight:	40Kg - 140 Kg
Height	150cm - 190cm

Calculated drug concentrations and effects are based on published models, and do not represent actual measurements from a patient. Drug models are calculated and displayed assuming a healthy patient.

Navigator Protocol allows facilities to load electronic versions of care protocols. This feature can be configured with selected patient monitoring parameters available for viewing in conjunction with the care protocol.

Navigator Device is a troubleshooting aid with access to certain Anesthesia Delivery System alarm information.

The system is designed for facility use and should only be used under the orders of a clinician.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Navigator Applications Suite has been updated from the predicate version (K081941, K071097). The Protocol and Device functionality is the same in the modified version as in the predicate version. There have been no changes to the intended use of the device.

The Therapy function of the Navigator Applications Suite has been modified to display predicted behavior of inhaled anesthetic agents based on the existing pharmacokinetic and pharmacodynamic models with predicted end-tidal anesthetic agent concentration values. The previously cleared Navigator Applications Suite displayed predictive models for intravenous drugs only.

The predicate version displayed multi-drug models for propofol and four analgesic drugs. This new software version is expanding the number of multi-drug models available in the system. There are new models for synergistic effects of six inhaled agents and four analgesics.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

Navigator Applications Suite has been thoroughly tested through verification of specifications and validation, including software validation. Verification of compliance with the following standards has also been made to support safe use of the device in its intended environment.

IEC 60601-1: 1988 A1: 1991, A2: 1995	Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-1-2: 2001	Medical Electrical Equipment, Part 2: Electromagnetic Compatibility– Requirements and Tests
EN 60601-1-4: 2000	Medical Electrical Equipment, Part 4 Programmable Electrical Medical Systems
EN 980;2003	Graphical Symbols for Use in Labeling Medical Devices
EN 1041: 1998	Information Supplied By the Manufacturer
EN ISO14971: 2000	Medical devices—Application of risk management to medical devices

SUMMARY OF CLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(2)

Additional testing of the Navigator Applications Suite was performed in a clinical setting to demonstrate the usability of the device. The results demonstrate that the device is usable in a clinical environment and does not introduce any hazards into the environment of use.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Navigator Applications Suite as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2009

GE Healthcare Finland OY
C/O Ms. Adrienne Lenz
Regulatory Affairs Manager
Datex-Ohmeda, Incorporated
PO Box 7550
Madison, Wisconsin 53707-7550

Re: K083098
Trade/Device Name: Navigator Applications Suite
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: March 4, 2009
Received: March 5, 2009

Dear Ms. Lenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K

Device Name: Navigator Applications Suite

Indications For Use:

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Prescription Use _XXX_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083099